Gillis, Diana L.

From: Walsh, Kathryn E.
Sent: Thursday, March 12, 2015 1:43 PM
To: [redacted]
Cc: Berg, Karen E.; Gillis, Diana L.; Whitehead, Nora
Subject: RE: Pharma license questions

Becky:

We do not think this license is reportable. If we understand correctly, at issue is the IP for the active pharmaceutical ingredient. Based on the facts below, the Licensor will still be able to use this IP for the same therapeutic area. Thus, the Licensee does not have all commercially significant rights to the active pharmaceutical ingredient in this therapeutic area. Let us know if we've mischaracterized what you've laid out.

Kate

From: [redacted]
Sent: Wednesday, March 11, 2015 10:23 AM
To: Walsh, Kathryn E.
Subject: Pharma license questions

Kate –

I hope you are doing well. I have a pharmaceutical license transaction and need some guidance on how to apply 801.2(g) where certain rights are reserved by the Licensor. Under 801.2(g)(3), patent rights are transferred if and only if all commercially significant rights to a patent, as defined in §801.1(o), for any therapeutic area (or specific indication within a therapeutic area) are transferred to another entity. 801.1(o) provides that the term "all commercially significant rights" means "the exclusive rights to a patent that allow only the recipient of the exclusive patent rights to use the patent in a particular therapeutic area (or specific indication within a therapeutic area)."

In this case, Licensor will grant to Licensee an exclusive license under the Licensed Intellectual Property (know-how, patents, trademarks) to Commercialize (market, sell and promote) Licensed Products (a currently available product and a different formulation pending FDA approval, both with the same active ingredient) in the Territory (US and some other designated countries).

The license granted to Licensee under the agreement is exclusive, even as to Licensor, for purposes of Commercializing the Licensed Products in the Territory. In addition, during the term of the agreement, Licensor will not seek FDA approval or allow any 3rd party to seek such approval for any product with the same active pharmaceutical ingredient, and will not grant any rights in any of the Licensed Intellectual Property to any third party for any purpose that includes developing, commercializing or manufacturing any dosage pharmaceutical product with the same active ingredient, subject to the reservation below. The Licensor retains the right to manufacture both of the licensed products for the Licensee

There is one significant reservation of rights for the Licensor, however. Licensor is currently developing a new pharmaceutical product that will include the same active pharmaceutical ingredient contained in the Licensed Products. This new product is in an early development stage. The FDA has not approved the new product for sale or marketing in the U.S. and it may never become commercial. But if the new product is ultimately developed, it would be used for the same therapeutic area as the Licensed Products, it would represent a significant upgrade in terms of case of administration , it would contain the same active pharmaceutical ingredient, and it could be sold in

the Territory by Licensor (subject to any rights Licensor may grant to any other third party). The Licensee's own internal view is that if the new product is over commercialized, it will largely cannibalize any market share that might have been gained by the products the Licensee is seeking to license from the Licensor.

In your prior guidance, you have made a distinction between a licensee having the exclusive right to the drug for a specific indication or therapeutic area with the licensor retaining the right to the same drug for other indications or therapeutic areas (reportable), and the licensee having the exclusive right to a particular formulation of a drug for certain indications and the licensor retaining the right to other formulations of the same drug for the same indications (not reportable). It appears to me that the license in this case falls into the latter category – the Licensor retains the right to other formulations of the same drug (i.e., the same active pharmaceutical ingredient) for the same indications (treating the same condition). However, that retained right is only for a potential product in development, not one that is currently commercial.

Under these circumstances, would the exclusive license being considered by the parties be deemed to include all commercially significant rights of the Licensor under the patents being licensed?

Thanks very much as always,

[redacted]

[redacted]

[redacted]